

D- START: Diabetes -Supporting TrAnslational Research Twinning

BRIDGES (Bringing Research In Diabetes to Global Environments and Systems), www.idfbridges.org is supported by a grant program dedicated to translational research¹ in diabetes, managed by the International Diabetes Federation (IDF) and established through a USD 10.000.000 educational grant from Eli Lilly and Company. BRIDGES was created to identify realistic ways of achieving better outcomes for people affected by diabetes, to support projects that test new hypotheses, and to close the gap between knowledge and needs, with the aim of preventing or slowing the progression of this disease. BRIDGES is already supporting projects that are expected to have impact on people living with diabetes and on the prevention of the condition worldwide.

BRIDGES funds two types of projects: Short term projects for a maximum of USD 65.000 and a maximum duration of 2 years; Long term projects for a maximum of USD 400.000 and duration of 3 years.

The first two rounds of funding were allocated in 2007 and 2009, the 3rd round of funding will occur from June 1st to October 1st 2010).

In addition to the original BRIDGES criteria for funding for the third round of funding, and to fit the gap of unmet needs and projects, IDF will launch a new initiative: D-START (Diabetes - Supporting TrAnslational Research Twinning) and dedicate USD 565.000 to it. The fund will be allocated as follow:

- USD 65.000 for the Coordinating Site²
- USD 250.000 per Implementation Site³ (2 projects from 2 Implementation Sites will be selected).

It must be stressed that this collaborative approach is intended to compliment the current BRIDGES process, not to substitute the original BRIDGES approach.

¹ "Translational research transforms currently available knowledge into useful measures for everyday clinical and public health practice. Translation research aims to assess implementation of standards of care, understand the barriers to their implementation, and intervene throughout all levels of health care delivery and public health to improve quality of care and health outcomes, including quality of life." (from Narayan et al. "Diabetes Translation Research: Where Are We and Where Do We Want To Be?" in Ann Intern Med, 2004; 140:958-963).

² **Coordinating Site** is the organization which propose the study design framework has been selected. It will be acting as Co Main Institution during the project, providing expertise and consultancy to the Implementation Site.

³ **Implementation sites** are the institutions which application forms based on the selected study design framework have been selected.

A- Aims of D-START

The aim of this initiative is to promote and facilitate the:

- ✓ Design and implementation of translational research projects on primary prevention of type 2 diabetes in Low and Middle income Countries⁴ (LMCs).
- ✓ Creation of an active and effective partnership between established researchers with expertise in primary prevention, paired with investigators working in LMCs and local Health Care authorities.
- ✓ Development of a critical number of trained researchers in LMCs who can continue working in the field of translational research activities after the BRIDGES grant is finished.
- ✓ Establishment of a long-standing partnership and scientific link between the research groups and LMCs.
- ✓ Implementation of research projects that will address the socioeconomic burden of diabetes and optimize the utilization of human and economic resources.

B- Selection criteria for the Coordinating Site (CS)

The role and experience of the CS will be crucial to the success of the new initiative D-START. The CS (university, NGOs, associations...) will be asked to design a framework of an intervention on prevention of type 2 diabetes which will be suitable for LMCS, develop and provide training on the framework to the 2 selected Implementation Sites, advise on the local adaptation of the framework and supervise both projects during the duration of the grant and beyond.

IDF is seeking the most recognized experts in interventions on primary prevention of type 2 diabetes to support this initiative by submitting an application.

As of January 15th 2010, the application form for the position of Coordinating Site will be available, upon request. Please contact Ronan L'Heveder, ronan@idf.org

The application form will only be sent to applicants who are considered acceptable to accommodate the position of Coordinating Site. The representative of the CS must have experience and credentials to provide support in epidemiology, clinical trials and diabetes primary prevention especially in LMCs. with publications in reputable peer reviewed journals published within the last 5 years.

⁴ As defined by the World Bank

The *Coordinating Site* should include in the application form template a:

✓ Generic outline of the framework for a study on the primary prevention of diabetes for a maximum duration of 3 years (starting 2nd semester 2011). The framework must contain a clear description of the various interventions, inputs and outputs required for successful implementation, the main milestones, the primary and secondary outcomes, and the expected results at the end of the project (based on the available literature). Applicants must consider:

- the maximum duration of the projects (3 years)
- funds available for the implementation site (USD250.000)
- the latest available deadline to start the project (October 2011)
- The time to get the IRB approvals in their country

✓ Description of how the institution will create, manage and ensure an efficient transfer of knowledge (preferably quoting previous experience(s)).

✓ List of key personnel involved from the *Coordinating Site*, their expected responsibilities in the project as well as their experience in working in LMCs.

✓ Description of their experience and credentials to provide support in epidemiology, clinical trials and diabetes primary prevention especially in LMCs, with publications in reputable peer reviewed journals published within the last 5 years.

✓ Description of the appropriate monitoring of quality control procedures that will be undertaken if selected.

The application should be completed with:

✓ Letter from the academic institution stating they will support the project and that the PI and team will have sufficient time to dedicate to the project to ensure its successful implementation during the all duration of the project.

✓ Draft budget of the *Coordinating Site* to support 2 projects, including the main budget lines and its justification considering IDF requirements (payment of low economy fares only); it would also include the development of the training materials⁵, one evaluation onsite per project and regular conference calls with grantees and the Advisory Committee. The proposed budget should only address the *Coordinating Site* component of the project, with a maximum of USD 65.000 to support 2 projects (one coordinating site will be selected and will support 2 projects). It should not take into consideration activities taking place before the selection of the 2 Implementation Sites.

⁵ ⁵ For this purpose, travel and accommodation for all study investigator (one representative for the coordinating site, one per implementation site) will be covered by IDF.

- ✓ The IRB approvals (if already available and required) as the CS will be in charge of the data analysis

C- Role of the CS during the project implementation

The Coordinating site will:

- ✓ Form part of an Advisory Group that will also include a representative of IDF and 2 experts designated by IDF. This group will have regular conference calls (one every 2 months) with the 2 implementation sites to ensure that the projects are going on the good direction and provide, if necessary, advices and suggestions.
- ✓ Participate in the project(s) evaluation which will take place just before the midterm of the project
- ✓ Provide feedback and advice to the Implementation Site when required
- ✓ Support data analysis of the data received by the IS

D- Selection criteria for the Implementation Sites (IS)

From June 2010, a template Letter Of Intent (LOI) will be available on BRIDGES website (www.idfbridges.org) alongside the documents for the 3rd round of funding.

In their LOI, The applicants will be required to demonstrate that they have:

- ✓ Not already implemented a similar study
- ✓ Sufficient resources (human and infrastructure) available for the project.
- ✓ A team able to manage such a project. The application should contain a clear description of each person involved in the project as well as their role and responsibilities in the project.
- ✓ The support (infrastructure, human and economic resources) and commitment of the local health authorities (local/regional/state/provincial healthcare institutions) to sustain and develop the project after the funding period.
- ✓ Particular advantages in carrying out the proposal in their specific location vis-à-vis the population, the availability of staff trained or willing to be trained in conducting the research.
- ✓ Willingness to work together with IDF and the selected coordinating site to refine the design of the project and the protocol.

Applicants will need to list any previous research and working relationships with international and foreign institutions in the development of projects linked to diabetes in the last 5 years.

Countries with limited research experience and who have limited funding resources will be favoured over those who have been regularly receiving local and foreign economic support. Applications from countries with available resources for research funds (as demonstrated by the implementation of an “international” project in the last 5 years) will have lower priority.

E- Role of the Implementation Sites (IS) during the project

The responsibilities of each project will be transferred to the each implementation site as soon as the agreement will be signed. These responsibilities included:

- Implementation of the project based on the inputs received by the Coordinating Site and the Advisory Board
- Management of the local staff
- Recruitment and management of participants for the study
- Production of materials for the intervention
- Data collection
- Implementation of the study design as developed and agreed with the CS
- Relations with local authorities
- Daily management of the project
- Financial management of the project
- Presentation of the project in congresses, magazines....(after approvals of the abstracts, articles... by the CS and the Advisory Board)
- Preparation and submission of the midterm and the final report
- Submission of the financial audit developed by an external auditing firm.

F- Legal responsibilities for CS and the 2 IS

The agreement is between the 3 parties (International Diabetes Federation, the Coordinating Site and the Implementation Site) and is under Belgian law.

After the training and the agreement has been signed, the Coordinating Site will act as an advisor and cannot be considered legally responsible for the failure of the project or problems encountered by the Implementation Site.

It is the responsibility of the Implementation Site to adapt the study design to the local circumstances (legal issues, IRB and ethical approvals, culture...) in order that it is feasible, and legally acceptable, to implement the project in the country.

Legal responsibilities D-START

Activity	Responsible party
Design framework study design	CS
Design application form	IDF
Complete application form	IS
Select application form	IDF + CS
Organize the training	IDF
Develop content of the training	CS + IDF
Adapt the study design to the local context	IS
Develop agreement	IDF
Sign the agreement	IDF + IS + CS
Obtain IRB approvals	CS and IS (depending on its role within the project)
Pay the instalments	IDF
Implement the project	IS
Monthly conference call to evaluate and, if necessary, adapt the project	IDF (for the organisation of the call), IS and CS (for the content)
Evaluate before mid term	IDF + CS
Midterm report	CS
Approve the midterm report	IDF + IS
Publicize the results	CS with a reference to IS
Promote the project	CS with a reference to IS
Final report and financial audit	CS
Sustain the project after the period of funding	CS in relation with IS

IDF: International Diabetes Federation

CS: Coordinating Site

IS: Implementation Site

G- Payment schedule

Payment of the grant will be done as follow:

For the Coordinating Site:

- 50% after the official announcement of the 2 Implementation Sites
- 20% at the signature of the agreement with the 2 Implementation Sites and IDF
- 20% after reception and acceptance by IDF of the midterm report
- 10% after acceptance, by IDF, of the final report and financial audit

For the Implementation Sites:

- 50% after the signature of the agreement with the Coordinating Site and IDF
- 40% after acceptance, by IDF, of the midterm report
- 10% after acceptance, by IDF, of the final report and financial audit.

H- Schedule of D-START in 2010

The call for tenders will divided into three phases:

Phase 1: Selection of a framework (January 15th -April 15th, 2010)

From January 15th to April 15th 2010, IDF BRIDGES will issue a Request for Proposals (RFP) to organizations with expertise to propose a framework for an intervention on primary prevention of diabetes which can be implemented via an Implementation Site⁶ in LMCs. The Request for proposal (FRP) will be organised around an application form which will be available upon request (please contact Ronan L'Heveder, ronan@idf.org) The proposed frameworks will be reviewed in May 2010 by a team of experts including members of BRIDGES Review Committee who will proceed with the final selection of the framework. The selected organization will be called Coordinating Site and will be lead by a Principal Investigator.

Phase 2: Selection of two projects (June 1st to October 1st 2010)

From June 1st to October 1st 2010, the selected framework will be proposed to organizations/institutions in LMCs which will need to complete a letter of intent (LOI)

⁶ **Implementation sites** are the institutions which application forms based on the selected study design framework have been selected.

describing how, if selected, they will implement the selected primary prevention framework and how the local healthcare organizations will participate in and support the project development. This procedure will take place in conjunction with the “usual” RFPs for the 3rd round of funding of BRIDGES. The LOI template will be available on the BRIDGES website (www.idfbridges.org)

In October 2010, a team of experts including the Principal Investigator of the Coordinating Site will review the LOIs received and decide which ones are eligible⁷ to submit a full application form. Applicants will be informed as soon as the results are known

Applicants whose LOIs are accepted, will receive a full application template which must be completed by January 15th 2011

The selection of the recipient(s) of the grant will be done during March 2011. To ensure feasibility of the project(s), the Principal Investigator of Coordinating Site will be invited to the selection process

Institution/organizations which have proposed the selected applications will be called Implementation Sites.

Phase 3: Agreement and training (March – June 2011)

The selected coordinating site will undertake, under the supervision of IDF, a training programme for the main investigator of the two selected projects (one participant per project) before the start of the 2 projects. During this training, parties will finalise details of the intervention and adapt the study design and interventions to the local context.⁸

The 2 selected projects will be supported by an Advisory Board composed of the PI of the coordinating site, a representative of IDF-BRIDGES and two international experts in the field of the selected projects selected by IDF.

⁷ To be eligible, a Letter Of Intent will need to respect the inclusion criteria as defined in the section “**Selection of Implementation Sites**”

⁸ For this purpose, travel and accommodation for all study investigator (one representative for the coordinating site, one per implementation site) will be covered by IDF.

I- Contact

For more information, please contact Ronan L'Heveder @ IDF

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